

REMARKS

The restriction requirement

Applicants acknowledge that the restriction requirement was deemed proper by the Examiner and was made final. Accordingly, non-elected Claims 40-79 have been cancelled without prejudice or disclaimer as being directed to a non-elected invention.

Election of species

Applicants have elected SEQ ID NO:16 as the species to be prosecuted on the merits. The Examiner alleges that Claim 39, which recites a composition of matter comprising a peptide which comprises SEQ ID NOS: 17, 18, 19 and 69 is not directed to SEQ ID NO:16 and is therefore further withdrawn from consideration. Applicants hereby cancel Claim 39 without prejudice or disclaimer as not reading on an elected species.

Claims 1-38 are currently pending in the application.

Oath or Declaration

The Examiner alleges that the oath or declaration is defective and a new oath or declaration is required because non-initialed and/or non-dated alterations have been made. Applicants intend to submit a new oath or declaration which is in compliance with 37 CFR 1.67(a).

Objections to the Drawings

In response to the objections to the drawings, Applicants submit herewith formal drawings and respond as follows.

In Figure 1, it is alleged that those sections designated Figure 1D, 1E and 1F are not mentioned in the description. Applicants have amended the description of Figure 1 to include reference to Figure 1D, 1E and 1F.

In Figure 7, it is alleged that several categories on the X-axis are neither listed nor explained in the specification. Applicants have amended the description of Figure 7 to refer to those categories on the X-axis. The amendment does not introduce new matter and finds support at p. 70, lines 20-28 of the specification.

In Figure 10, it is alleged that the designations "10A, 10B, 10C" are neither listed nor explained in the specification and that the X-axes of the top two figures are not labeled. Applicants have submitted corrected drawings and amended the description of Figure 10 to refer to "10A, 10B, and 10C".

In Figure 11, it is alleged that the designations "11A, 11B, 11C, 11D" are neither listed nor explained in the specification. Applicants have amended the description of Figure 11 to refer to same.

Objections to the Claims

Claims 1-38 are objected to because they recite non-elected species. Applicants note that the Examiner has required an election of species for prosecution on the merits to which the claims shall be restricted if no generic claim is held to be allowable. Moreover, upon allowance of a generic claim, additional species will also be considered. Claim 1 is a generic claim. As the allowability of Claim 1 and other generic claims which encompass the elected species has not yet been determined, Applicant maintain that it is premature to correct the pending claims because they recite non-elected species. It is maintained that the claim objections be held in abeyance pending a determination of allowable subject matter.

Rejection under 35 U.S.C. 101

Claims 1-38 are rejected under 35 U.S.C. 101 as the claimed invention is allegedly drawn to a product of nature. The Examiner has suggested introduction of terms such as "isolated" or "substantially pure" in order to overcome the rejection.

Applicants traverse the rejection as the composition of Claim 1 is not a product of nature but is in fact a non-naturally occurring product of nature. Claim 1 recites a PTH/PTHrP modulating domain (designated as P¹) to which is attached a vehicle (designated as F¹) wherein the attachment may or may comprise a linker (designated as L¹). The combination of a PTH/PTHrP modulating domain and a vehicle (which may be, for example, an Fc domain) is not a product of nature but may be manufactured according to the teachings of the specification. A similar argument would apply even in view of Applicants' species election of SEQ ID NO:16. In this instance, the combination of SEQ ID NO:16 as the PTH/PTHrP modulating domain and a vehicle is not a product of nature. Thus, it is not necessary to indicate that the composition is "isolated" or "substantially pure". Withdrawal of the rejection is requested.

Rejection under 35 U.S.C. 112

Claims 31, 36 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for recitation of the following: Table 1 in Claim 31, Table 2 in Claim 36 and Table 4 in Claim 38. The Examiner argues that the claims are not complete.

Without acquiescing to the rejection and solely to advance prosecution, Applicants have amended Claims 31, 36 and 38 to indicate the SEQ ID NOS listed in Tables 1, 2 and 4, respectively. The amendments do not introduce new matter and are supported by the disclosures in the referenced tables. Withdrawal of the rejection is requested.

Rejection under 35 U.S.C. 102

Claims 1-38 are rejected under 35 U.S.C. 102(b) as being anticipated by any one of U.S. Patent No. 5,556,940 (hereafter the "940 patent"), U.S. Patent No. 5,589,452 (hereafter the "452 patent") and U.S. Patent No. 5,693,616 (hereafter the "616 patent"). The Examiner argues that each patent discloses SEQ ID NO:1, a 34 residue long peptide that shares 100% homology to SEQ ID NO:16 of the instant application.

In order for a reference to anticipate claimed subject matter, it must disclose each element of the claimed invention *Atlas Powder Co. v. E.I. duPont de Nemours & Co.* 224 USPQ 409, 411 (Fed. Cir. 1984). Moreover, the prior art must be enabling and a method for making a claimed product must be disclosed by the prior art. *In re Donahue* 226 USPQ 691, 621 (Fed. Cir. 1985). Claim 1 recites a PTH/PTHrP modulating domain to which a vehicle is attached with or without an intervening linker sequence. The definition of a vehicle is set forth at p. 14, line 24 to p. 15, line 7 of the specification. In response to the species election requirement, the PTH/PTHrP modulating domain was elected to have the sequence of SEQ ID NO:16. Accordingly, Claim 1 is being examined as reciting a PTH/PTHrP modulating domain of SEQ ID NO:16 to which a vehicle is attached, with or without an intervening linker sequence.

Applicants traverse the rejection as improper as the cited reference fail to disclose each element of the claims and fail to enable the claimed invention. The '940, '452 and '616 patents only disclose a sequence of PTH[1-34], which is identical to SEQ ID NO:16 but does not disclose a vehicle attached to SEQ ID NO:16 and does not disclose a linker through which the vehicle may be attached to SEQ ID NO:16. Accordingly, the references fail to disclose each element of the claimed invention and do not anticipate the invention. Moreover, there is no disclosure in any of the cited patents of a method for making SEQ ID NO:16, which is attached to a vehicle, optionally with an intervening linker. The disclosures are concerned solely with the chemical synthesis of PTH[1-34] alone with no teachings of attaching a vehicle with or without a linker. Accordingly, the references fail to enable the claimed invention.

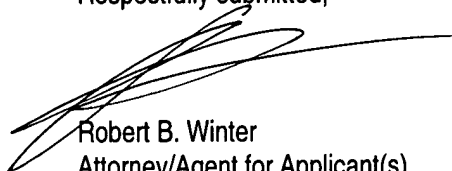
The Examiner appears to have examined the claims as if the only claim element was the amino acid sequence set forth in SEQ ID NO:16. Applicants respectfully remind the Examiner that the claims are not being restricted such that SEQ ID NO:16 is the sole claim element. Applicants elected to prosecute the subject matter of Group I, Claims 1-39 (as set forth in the restriction requirement of September 19, 2002) with the further species election of SEQ ID NO:16 within the invention of Group I for prosecution on the merits. This species election does not act to restrict out other aspects of the invention, such as the attachment of a vehicle and the presence of a linker. It is requested that examination be carried out with respect to the full extent of elected subject matter.

For the reasons set forth above, the rejection may be withdrawn.

CONCLUSION

Claims 1-38 are in condition for allowance and an early notice thereof is solicited.

Respectfully submitted,



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